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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,772	08/18/2003	Meir Rosenberg	022719-0046	3663

21125 7590 10/04/2007  
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BOSTON, MA 02210-2604

EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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10/04/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p align="center">10/642,772</p>	<p>Applicant(s)</p> <p align="center">ROSENBERG, MEIR</p>	
	<p>Examiner</p> <p align="center">Jeffrey G. Hoekstra</p>	<p>Art Unit</p> <p align="center">3736</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-11, 13, and 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (US 5,291,896) in view of Purdy et al (US 2003/0097082 A1).
3. For claims 1 and 18, Fonger et al discloses a catheter drainage system as broadly as *structurally* claimed, comprising: an elongated tube, or catheter, 12 including a distally disposed solid state pressure transducing sensor 14 (column 6 lines 1-41) as best seen in Figures 1 and 2 and (b) said sensor *functions* to measure pressure adjacent the external surface of the distal-most end of the catheter (column 5 lines 4-20 and column 6 lines 1-41), further including at least one wire 24 distally coupled to the sensor and proximally mated to an apparatus for electrical powering or communicating that extends along the length of the catheter in fluid isolation from the inner lumen 40 and wherein the at least one wire being proximally separable from the elongated tube through a slit 46 such that the tube length is selectively adjustable (column 2 lines 30-35 and column 4 lines 32-44)). Furthermore, the slit 46 extends through the outer wall 15 of the tube 12 into the second lumen 42 such that the at least one wire can be partially removed to adjust the tube length.

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4. For claims 2 and 11, Fonger et al discloses the at least one wire 24 disposed within a second lumen 42 isolated from the first and wherein the slit 46 extends into the second lumen).

5. For claim 3, 6-10, and 21-24, Fonger et al discloses a slit 46 extending through the outer wall 15 of the tube 12 into the second lumen 42 such that the tube length is selectively adjustable (column 4 lines 32-44). The slit 46 is configured such that the at least one wire can be partially removed to adjust the tube length and when said wire(s) is/are inserted they are in substantial fluid isolation via the sealing action of the polymer. The slit 46 is configured (column 4 lines 6-10) to extend along a distance less than the length of the catheter and less than about one half the length of the catheter as best seen in Figure 1.

6. For claims 4 and 19, Fonger et al discloses a first lumen diameter greater than the second lumen diameter (column 3 lines 60-66).

7. For claims 5 and 20, Fonger et al discloses multiple secondary lumens 84,86,88,90 formed within an invagination of the outer tube wall 12 as best seen in Figure 7.

8. For claims 13 and 25, Fonger et al discloses the use of a flexible, biocompatible polymer (column 3 lines 41-42).

9. For claims 15-17 and 26-27, Fonger et al discloses a distally disposed pressure sensor (column 6 lines 13-18) adapted to sense physiological conditions adjacent to the elongated tube and disposed within the secondary lumen with an inner diameter of 10 French (column 3 lines 63-66) which is equal to approximately 3.3 mm or 0.131 inches.

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10. Thus for claims 1-11, 13, and 15-27, Fonger et al discloses the claimed invention except for explicitly disclosing (a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna. Purdy et al teaches (a) a distally disposed pressure sensor (94) embedded in a distal portion of the catheter (as best seen in Figure 14, 15, and 17) (paragraph 132) and (b) at least one wire having a proximal end mated to an external antenna (wire element 96, paragraph 133). The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Fonger et al and Purdy et al teach pressure measurement catheters, it would have been obvious to one skilled in the art at the time of the invention to substitute one distally disposed pressure sensor configuration for the other to achieve the predictable results of measuring a pressure of fluid surrounding the distal portion of the catheter via a distally disposed pressure sensor configuration in a pressure measurement catheter system.

11. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Purdy et al and in further view of Quackenbush (US 5,104,398). Fonger et al in view of Purdy et al discloses the claimed sensor catheter drainage system except for (a) the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and (b) the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary

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catheter. Quackenbush discloses a membrane splitting tube 10 comprised of polyurethane (column 3 line 23) with a catheter or wire inserted in an outer peel-away membrane (column 1 lines 33-41). The claim would have been obvious because a person of ordinary skill at the time of the invention would have a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. Thus, it would have been obvious to a person of ordinary skill in the art at the time of the invention to try using a polyurethane catheter with a secondary catheter or wire inserted in an outer peel-away membrane as taught by Quackenbush in an attempt to provide a catheter with a selectively adjustable length, as a person with ordinary skill has a good reason to pursue the known options within his or her technical grasp. In turn, because the catheter, wire, and secondary catheter as claimed have the properties predicted by the prior art, it would have been obvious to make a catheter having at least one wire running therethrough, which is coupled to a sensor disposed at a distal portion of the catheter, and wherein an outer peel-away membrane is provided to selectively adjust the length of a catheter.

### ***Response to Arguments***

12. Applicant's arguments, see pages 2-3, filed 04/27/2007, with respect to the rejection(s) of claim(s) 1-11, 13, and 15-27 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Purdy et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a

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new ground(s) of rejection is made in view of a different interpretation of the previously applied reference and a new ground(s) of obviousness.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

  
MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700